Patent
Attorney's Docket No: 700974-2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

David FIKSTAD et al.

Group Art Unit: 1618

Application No.: 09/871,318

Examiner: Micah Paul Young

Filed: May 31, 2001

Confirmation No.: 1207

For: TRANSDERMAL DELIVERY OF LASOFOXIFENE

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Reply Brief is filed in response to the Examiner's Answer dated September 28, 2007. This Reply Brief is being filed under the provisions of 37 CFR § 41.41

REMARKS

Examiner's Answer

In the Examiner's Answer, the Examiner sustained his prior rejections of pending claims 3-5, 14, 17-19, 22-39. The Examiner rejected claims 3-5, 14, 17-19, 22-40 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 6,203,817 to Cormier *et al.* ('817) and U.S. Patent No. 6,323,232 to Ke *et al.* ('232).

The Examiner also asserted that due to a "typographical error" claim 40 was not rejected. The Examiner then took the position that "the claims would have been rejected in any of the previous office actions, and is rejected now." This is the only place where claim 40 has been treated as a finally rejected claim.

Claim Rejections Under 35 U.S.C. § 103(a)

On pages 3-5 of the Examiner's Answer, the Examiner rejected claims 3-5, 14, 17-19, 22-40 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of the '817 patent and the '232 patent. While the Examiner's rejections are similar to the generalized rejections made in the final Office Action, the Examiner has only now attempted to apply the patent publications to the elements in each of the claims. This can readily be seen by comparing the non-final and final Office Actions with the Examiner's Answer. The Examiner's belated effort in this regard, however, does not fulfill his burden under 35 U.S.C. § 103.

The Examiner provided additional arguments on pages 5-8 in the "Response to Argument" section of the Examiner's Answer. Specifically, the Examiner asserted that the '817 patent and the '232 patent disclose every limitation of the appealed claims either explicitly or inherently. These assertions, however, are insufficient to demonstrate that the instant claims would be obvious to one of ordinary skill in the art. Instead, they are, once again, generalized

arguments that do not take into account the difficulties involved with formulating pharmaceuticals in a vehicle that enable their transmission across the skin barrier and into systemic circulation. The Examiner has only attempted to find each of the claim elements in a published document and then assert that combining these publications could be accomplished through optimization by one of ordinary skill in the art, based on generic arguments describing the level of ordinary skill in the art.

The road block, however, to one of ordinary skill combining the '817 patent and the '232 patent is that they are directed to different formulations (gel patch device vs. solution/suspension) containing pharmaceuticals having very different chemical properties. The only common thread in these two patents is their discussion of anti-estrogenic compounds.

However, as discussed in detail in Applicants' Appeal brief, the differences in the chemical properties of the pharmaceuticals in the '817 and '232 patent teach away from combining these two patents. In response, the Examiner alleges that, despite the differences in chemical structure, the compounds disclosed in the cited patents are "functional" equivalents, and that one of ordinary skill in the art would be aware of the changes in formulation that would be required. The Examiner further alleges that these changes only require routine experimentation and optimization to implement.

The Examiner's argument continues to be based on the false presumption that drugs of the same pharmacologic class possess similar chemical properties and characteristics. There is no basis in fact or law for the Examiner's presumption that compounds with similar pharmacological activities necessarily have similar chemical properties. Although it is a well-established principle of patent law that compounds of similar structure are presumed to have

similar properties (*See, e.g. In re Dillon,* 919 F.2d 688, 692-693; 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990), there is no authority for the converse proposition articulated by the Examiner.

The Examiner dismisses the formulation differences (gel patch device vs. solution/suspension) in the cited patents by asserting that the '232 reference is only being used to cite "lasofoxifene in transdermal formulation [sic] comprising propylene glycol, ethanol, glycerin and other emulsifiers common in the art and shared by the '817 patent." However, this does not negate the fact that the different formulations teach away from their combination. One of ordinary skill in the art could not simply take a solution/suspension and convert it to a transdermal formulation. Each of these phases contains different additives with diverse chemical properties that impart physical properties resulting in a gel, suspension or solution. To equate these phases disregards their distinct nature. In fact, since the '232 patent does not discuss transdermal delivery systems at all, there is no suggestion that its disclosure could be combined with the '817 patent, which only teaches that a solution, such as a parenteral solution, may be applied topically to the skin. A solution, however, is far from the transdermal drug delivery system claimed in the instant application.

As in the non-final and final Office Actions, the Examiner fails to present arguments relating to the elements in each of the claims. Instead, the Examiner misconstrues the cited patents, asserts that claim limitations carry little weight and generally argues that the publications disclose the elements of the claims without citing where the elements may be found in each asserted cited patent. All of these assertions, however, do not represent a *prima facie* case of obviousness.

An example of how the cited patents have been misconstrued relates to the peel seal disc. In the Answer, the Examiner asserted that part 24 in Figure 2 in the '817 patent would act as a

protective peel seal disc. Part 24 (*see* col. 9, lines 56-58), however, is a release liner that is entirely different than the peel seal disc claim element. This is because the release liner is element G of independent claim 14 in the instant application whereas the peal seal disc is described in elements a, b, and e of claim 14. While the terminology is similar among the claim elements and the cited patents, their functions differ. As a result, the Examiner's assertions and application of the cited patents are improper and demonstrate the inexact manner in which this patent application has been examined.

The Examiner's dismissal of the heat limitation in the claims also demonstrates the extent to which the Examiner has not carried his burden in setting forth a *prima facie* case of obviousness. For example, in response to the arguments presented in the Appeal Brief, the Examiner merely asserted that the heat seal limitation is a product-by-process limitation and does not impart patent ability to the claims. The flaw in this response is that the sealed portion in the '817 patent does not correspond to what is sealed in the instant application. For instance, the subject application uses heat to seal three layers (the peel seal disc, the active agent permeable membrane and the backing layer), whereas the '817 patent seals only two layers (the backing layer and either rate controlling membrane or tie layer membrane). The result of this difference is that the heat seal in the '817 patent does not render obvious the heat seal in the instant claims.

Finally, in regard to the methods of claims 17 and 32, the Examiner responds to the arguments presented in the Appeal Brief by generally arguing what the '817 and '232 patents disclose without citing the locations of any of the elements of the rejected claims in the cited patents. The Examiner then asserted that it would have been obvious to combine the publications. The Examiner's inexact arguments do not demonstrate that the any of the claim

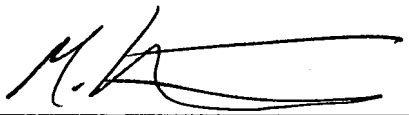
elements are actually found in the publications and as a result the Examiner has not carried his burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103.

Conclusion

In view of the foregoing arguments, the Appellant respectfully requests reconsideration and withdrawal of the claim rejections, and that the application be passed to issuance. Failing that, the Appellant respectfully requests the Board to overrule the Examiner's rejections, based on the explanations presented above and in the Appeal Brief, and to pass this application to issuance.

The Commissioner is hereby authorized to charge the brief fee set forth in 37 C.F.R. § 41.20(b)(2) and any insufficiency or credit any overpayment associated with this application to Bingham McCutchen LLP Deposit Account No. 50-4047.

Respectfully Submitted,



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